



September 16, 2013

BY E-MAIL (sullivanysdchambers@nysd.uscourts.gov)

Honorable Richard J. Sullivan
 United States District Judge
 United States District Court
 Southern District of New York
 500 Pearl St., Room 615
 New York, NY 10007

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Re: *Enzo Biochem, Inc. et al. v. Amersham plc, et al.*
No. 02 CV 8448 (RJS) (S.D.N.Y.)

Dear Judge Sullivan:

Pursuant to the Court's direction at the August 30, 2013 hearing, this letter is submitted jointly on behalf of Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (collectively, "Enzo"), and Amersham plc and Amersham Biosciences (collectively, "Amersham") concerning the parties' positions regarding thirty-four (34) products that Enzo contends remain at-issue in this litigation and properly stand accused of patent infringement ("the Products-at-Issue").¹

I. Enzo's Position

Enzo's position is that the Products-at-Issue remain in the case and Enzo's claims of patent infringement against those products should be tried. On March 9, 2005, Enzo identified 108 Amersham products (including the Products-at-Issue) in response to Amersham's Interrogatory No. 18, as infringing the patents-in-suit, along with the information Enzo had available to it at the time concerning those products. With respect to the Products-at-Issue, Enzo lodged an objection that Defendants had not provided sufficient discovery, including chemical structures, to more fully respond. In many instances, Enzo included claim charts showing an element-by-element analysis of how specific patents were infringed by specific categories of products, with footnotes identifying the products corresponding to that category, including several of the Products-at-Issue. For other Products-at-Issue, Enzo was unable to provide such an element-by-element analysis, because, despite Enzo's requests, Amersham had not produced chemical structures or other documentation concerning these products. Enzo listed them at the end of its interrogatory response, stating that those products "may infringe one or more claims from the patents-in-suit," but that "due to limited documentation produced by Amersham, Enzo is unable to provide a limitation-by-limitation infringement analysis...."

¹ The Products-at-Issue are identified by name and product code in the attached Exhibit A. Enzo believes that the Products-at-Issue may infringe at least one claim of each of U.S. Patent Nos. 5,328,824 and/or 5,449,767.

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 CHICAGO
 DALLAS
 DELAWARE
 DENVER
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 HOUSTON
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 LONDON
 LOS ANGELES
 MEXICO CITY
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 MILAN
 NEW JERSEY
 NEW YORK
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 ORLANDO
 PALM BEACH COUNTY
 PHILADELPHIA
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 ROME
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On September 21, 2006, following Judge Sprizzo's claim construction order, Enzo supplemented its response to Amersham's Interrogatory No. 18, again subject to an objection that Amersham had still not provided sufficient discovery to fully respond. Where possible, Enzo provided more detailed charts for many accused products after analysis of Amersham's belatedly-produced documents. However, for the Products-at-Issue, Amersham *still* had not produced the most basic documentation concerning those products, including their chemical structures. Again, for those particular products, Enzo listed them within the interrogatory response (but before the claim charts), stating: "However due to Amersham's production of documents that do not depict the chemical structures of the products themselves and/or any labels/labeled products that are instructed/recommended to be used with Amersham's products, Enzo is unable to provide a limitation-by-limitation infringement analysis."

Judge Sprizzo *never* held that products identified but not charted in March 2005 were "out of the case."² In fact, Judge Sprizzo never once used the term "claim chart." Each of the Products-at-Issue were specifically identified in March 2005, again in September 2006, and were the subject of discovery requests which, to this day, Amersham has refused to respond to and produce documents that Enzo has been requesting for years.³ Amersham should not be able to ignore legitimate discovery requests and then be rewarded by precluding Enzo from asserting patent claims against the Products-at-Issue based on its failure to abide by its discovery obligations; to do so would be to turn discovery on its head. Moreover, the alleged "incompleteness" of Enzo's response was addressed by a *valid objection* to the interrogatory—i.e., that discovery into the structures and other basic information about the Products-at-Issue was required for Enzo to provide a detailed claim chart. Amersham refused to provide such documentation despite numerous letters from Enzo in a good faith effort to resolve this dispute.

At the August 30, 2013 hearing, Amersham asserted that the Products-at-Issue are "structurally identical" to products on which Amersham was granted summary judgment.⁴ (See Aug. 30, 2013 Hr'g Tr. at 54.) If Amersham were simply to produce documents on these 34 products, Enzo would be able to verify that this is the case and perhaps concede noninfringement pending the resolution of any appeal of Judge Sprizzo's construction. But to date, the only information Enzo has on "structural identity" is the assertion of Amersham's counsel. And Enzo has reason to believe (including in the admissions of Amersham's witnesses at deposition and the Amersham documents produced thus far), that at least some

² Enzo's September 2006 interrogatory response identified several other products that were not in its March 2005 interrogatory responses. When Amersham raised this issue before the Court, Judge Sprizzo held that those products could not be asserted in this action but needed to be included in a "new or supplemental complaint." (Oct. 26, 2006 Hr'g Tr. at 26:5-13.) The same is *not true*, however, with respect to the Products-at-Issue.

³ See, e.g., Plaintiffs' First Set of Requests for the Production of Documents and Things to the Amersham Defendants, dated Jan. 22, 2003, Request Nos. 8-9, 19-22, 27-32, 35-49, 60-61; Enzo's Third Set of Requests for Production of Documents to Amersham, dated Mar. 9, 2005, Request Nos. 2-4, 52-56, 58.

⁴ We note that in September, 2006 counsel for Enzo asserted in a letter to Amersham's counsel that "most of the newly added products are identical to products already accused of infringement or in the same family." See Dkt. 296 at Exhibit 38. The "newly added products," though, referenced the products newly accused in September, 2006, not the Products-at-Issue that Enzo accused on March 9, 2005 of infringing.

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of Amersham's Products-at-Issue are not only capable of indirect detection, but are in fact used in this fashion. For this reason, Enzo does not agree that this issue should be deferred until a decision from the Federal Circuit on Judge Sprizzo's claim construction.

Accordingly, Enzo respectfully submits that the Products-at-Issue should be deemed "in the case" and subject to Enzo's surviving patent claims. If Amersham contends that these products are covered by the prior non-infringement summary judgment ruling, then Amersham should be ordered to produce documents showing the chemical structures of the Products-at-Issue (including kit components, where applicable), and labels/labeled products that are instructed/recommended to be used with the Products-at-Issue, so that such a determination might be made.

II. Amersham's Position

Enzo's position can be distilled down to two remarkably untimely requests: (i) a motion to compel discovery (despite the May 2005 fact discovery cutoff) and (ii) a request for leave to assert a new infringement theory depending on its assessment of such discovery (despite the March 2005 deadline for contention interrogatory responses). These requests should be rejected out of hand. This case has been pending for nearly eleven years and Enzo's opportunity for discovery and to formulate its infringement contentions has long since passed. Amersham sought and, in September of 2012, obtained summary judgment of non-infringement for the products which, at the time of filing of its motion, stood timely accused under an articulated theory of infringement. Nothing remains for adjudication on Enzo's patent claim, and Enzo's thirteenth-hour attempt to find a new theory of liability that certain Amersham products may have been "in fact used" for "indirect detection" -- of which even Enzo appears unsure at present -- should be rejected for several reasons.

First, it cannot reasonably be disputed that Enzo was operating under a March of 2005 deadline for disclosing its infringement theories. By way of background, Amersham served at the outset of the case, in 2002, Interrogatory Number 18, which sought detailed infringement contentions from Enzo, including a claim chart with a limitation-by-limitation analysis. Dkt. 296-2 Ex. 20 (No. 18 of Amersham's First Set of Rqs). After Enzo repeatedly refused to provide the requested information, and with claim construction proceedings looming in early 2005, the defendants sought relief from the Court to ensure they understood what was truly at issue for purposes of claim construction and the case as a whole. Judge Sprizzo made clear that Enzo was obligated to complete its response to contention interrogatories in March of 2005, before the parties engaged in claim construction proceedings. His instructions were unambiguous: ***"I will suggest, if there's going to be amended answers to interrogatories previously [served], it be done in 30 days from now. Then after, I will not entertain anything further. And any changes to interrogatory answers, I have to know for my own benefit what I'm going to be asked to be resolved . . ."*** Dkt. 296-3 Ex. 21 (2/7/2005 Hrg. Tr.) at 10:11-16 (emphasis added).

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Second, Amersham moved for summary judgment of non-infringement on the only infringement theories that Enzo disclosed prior to the March 2005 deadline and the products that stood accused under such theories at the time it filed its motion. Remarkably, Enzo does not contend that Amersham somehow failed to address a timely-asserted infringement contention within its summary judgment papers. Instead, Enzo seeks discovery to see whether it may have a new and previously undisclosed theory that certain products were “in fact used” for “indirect detection,” which not even Enzo appears certain that it has a Rule 11 basis to assert.⁵

To the extent that Amersham did not address, in its summary judgment papers, any of the products that Enzo now identifies, it is because they did not stand accused under any particular patent claim or under any identified infringement theory at the time of Amersham’s motion. Enzo listed 10 of those products in its March 2005 interrogatory response among a lengthy recitation of products that “may” infringe one or more unspecified claims of the patents-in-suit (of which there were originally 9 asserted patents), without any indication of which claims those products might be alleged to infringe or under what theory.⁶ For the vast majority of the other products Enzo contends are still at issue, Enzo accused them in March of 2005 of infringing the ‘767 and ‘824 patents and provided the exact same limitation-by-limitation analysis as the products for which Amersham moved for -- and obtained -- summary judgment (Dkt. 296 Ex. 23 (attached claim chart) at 1-20 (filed under seal); Dkt. 280 at 10-12); however, Enzo dropped its contention that those products infringed such patents in a September 2006 supplemental interrogatory response and indicated instead only that they “may” infringe one or more unspecified claims of the 9 patents-in-suit without any specific infringement theory.⁷ Dkt. 318-4

⁵ Enzo’s position recited in footnote 1 that “Enzo believes that the Products-at-Issue *may* infringe *at least one claim of each of U.S. Patent Nos. 5,328,824 and/or 5,449,767*” would not pass muster at the pleading stage let alone after more than a decade of litigation. *See supra* n. 1 (emphasis added).

⁶ Those products are: ALFexpress dATP Labeling Mix (27-2694-01), AlkPhos Direct Hybridization Buffer (RPN 3688), AlkPhos Direct Labeling and Detection System with CDP-Star (RPN 3690, RPN 3691), AlkPhos Direct Labeling and Detection System with ECF (RPN 3692), AlkPhos Direct Labeling Module (RPN 3680, RPN 3681), CDP-Star Detection Reagent (RPN 3682, RPN 3683), DYEnamic ET Dye Terminator Kit (MegaBACE) (US 81090, US 81095), DYEnamic ET Terminator Cycle Sequencing Kit (US 81050, US 81060, US 81070), ECF Detection Module (RPN 3685), Fluore-dATP Labeling Mix (27-1696-01). *See* Dkt. 296 Ex. 23 (attached claim chart) at 21 (filed under seal).

⁷ Those products are: AutoRead 200 Sequencing Kit (27-1791-12), AutoRead 1000 Sequencing Kit (27-1791-01), AutoRead Sequencing Kit (27-1690-04), CDP-Star Detection Module (RPN 3510, RPN 3511), Cy3-CTP (25-8010-86), Cy5-CTP (25-8010-87), ECF Detection Module (RPN 5750), ECL 3'-Oligolabeling and Detection System (RPN 2131), ECL 3'-Oligolabeling Module (RPN 2130), ECL Detection Reagents (RPN 3004, RPN 2105), ECL Random-Prime Labeling and Detection System (RPN 3030, RPN 3031), ECL Random-Prime Labeling System (RPN 3040), Fluoro Blue (coumarin-11-dUTP) (RPN 2123), Fluoro Green (fluorescein-11-dUTP) (RPN 2121), Fluoro Red (rhodamine-4-dUTP) (RPN 2122), Gene Images 3'-Oligolabeling (RPN 5770), Gene Images 3'-Oligolabeling and CDP-Star Detection System (RPN 5776), Gene Images 3'-Oligolabeling and ECF Signal Amplification System (RPN 5775), Thermo Sequenase Cycle Sequencing Kit (US 78500), Thermo Sequenase DNA Polymerase (E79000Y, E79000Z), Thermo Sequenase Dye Terminator Cycle Sequencing Premix Kit (US 79765, US 79865, US 79965), Thermo Sequenase II Dye Terminator Cycle Sequencing Kit (US 82005, US 82010, US 82015), Thermo Sequenase II Dye Terminator Matrix Standards (US 80985). *See* Dkt. 318-4 at 3-8. Finally, Thermo Sequenase Dye Terminator Cycle Sequencing Core Kit (Product No. US 79565) was dropped entirely from Enzo allegations after 2005 and Enzo’s infringement

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at 3-8. Enzo's apparent belief that it could forestall complete resolution of its patent claim by noting simply that it "may" have additional unstated theories is without any procedural support and contrary to Judge Sprizzo's rulings.

Third, Enzo's attempt to pass the blame for its non-compliance with the March 2005 contention interrogatory deadline is misplaced. Amersham is not aware of any supportive authority for the notion that a party can obtain relief from a court-ordered disclosure deadline simply by noting an "objection" in its discovery response that it feels dissatisfied with the other party's document production. If Enzo truly believed that it had a discovery dispute with Amersham that prevented it from providing final contention interrogatory responses in March of 2005 per Judge Sprizzo's ruling, the only proper course of action was to bring the issue to the Court. Yet, Enzo never raised its current discovery grievance with Judge Sprizzo prior to the deadline for amended interrogatory responses or the fact discovery cutoff (despite the numerous hearings in this case). Instead, Enzo raised the issue only after issuance of the claim construction ruling and after Amersham indicated it planned to move for summary judgment. As Amersham explained at that time, even if additional products had been timely accused in the case, Amersham had already produced the related documents in its possession, and Amersham remains unaware of any product materials sought by Enzo (which given the expiration date of the relevant patents would have been from the 1996 to 2004 timeframe) that have yet to be produced. (Dkt. 296-7 Ex. 25 (9/12/2006 letter from M. Wolf to R. Chern); *see also* Dkt. 296-8 Ex. 26 (3/5/2007 letter from A. Whiting to R. Chern)).

Fourth, Enzo's suggestion that Judge Sprizzo did not foreclose Enzo's present efforts to obtain additional discovery with the aim of advancing a new infringement theory also strains credulity. Judge Sprizzo stated in late 2006:

We are not going to start the ball anew or the ball rolling again every time [Enzo's counsel] comes up with a new theory. There has got to be an end to discovery. . . . At this stage of the case after I have expended the time and effort, and a considerable amount of time on the Markman hearing and writing an opinion, right or wrong, I am not about to have the theory of the case shift to new items and new claims that were not asserted in the original complaint or that were not part of the Markman[] hearing.

(Dkt. 296-9 Ex. 27 (10/26/2006 Hrg. Tr.) at 23-27 (emphasis added).) Although Enzo now suggests that it is not trying to raise a new theory or item, Enzo's new potential "indirect detection" theory of infringement was *never* timely disclosed, in its operative complaint or in any discovery responses. (Dkt. 70 at 25-27; Dkt. 296-5 Ex. 23 (filed under seal).)

contention as to the Cy3-dCTP product (Product No. PA 53031) is subsumed in the same contention against the Cy3-dCTP product (Product No. PA 53021), which was adjudicated by this Court to be non-infringing. *Compare* Dkt. 269-22 at 8-10; Dkt. 269-27 at 9-10; Dkt. 269-48 at 7-9; Dkt. 269-56 at 7-8, *with* Dkt. 253-23 at 1 *and* Dkt. 280 at 10-12.

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Finally, the prejudice to Amersham would be palpable should Enzo be permitted another round of discovery and to advance a new theory of liability. Not only is this unusually prolonged litigation at an advanced stage, the two patents that Enzo contends remain at issue expired in December of 2004, and thus, the events in question predominantly occurred over a decade ago. Amersham has already expended significant time and resources to defend the litigation and any new infringement contentions could well necessitate further claim construction, expert discovery and an additional summary judgment proceeding. Amersham thus respectfully requests that Enzo not be permitted to start the “ball rolling again” to explore a new theory of patent liability.

Respectfully submitted,

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cc: Matthew M. Wolf
Jennifer A. Sklenar

EXHIBIT A—Products Enzo Contends Are At Issue

Prod. No.	Name
25-8010-86	Cy3-CTP
25-8010-87	Cy5-CTP
27-1690-04	AutoRead Sequencing Kit
27-1696-01	Fluore-dATP Labeling Mix
27-1791-01	AutoRead 1000 Sequencing Kit
27-1791-12	AutoRead 200 Sequencing Kit
27-2694-01	ALFexpress dATP Labeling Mix
E79000Y, E79000Z	Thermo Sequenase DNA Polymerase
PA 53031	Cy3-dCTP
RPN 2121	Fluoro Green (fluorescein-11-dUTP)
RPN 2122	Fluoro Red (rhodamine-4-dUTP)
RPN 2123	Fluoro Blue (coumarin-11-dUTP)
RPN 2130	ECL 3'-Oligolabeling Module
RPN 2131	ECL 3'-Oligolabeling and Detection System
RPN 3004, RPN 2105	ECL Detection Reagents
RPN 3030, RPN 3031	ECL Random-Prime Labeling and Detection System
RPN 3040	ECL Random-Prime Labeling System
RPN 3510, RPN 3511	CDP- <i>Star</i> Detection Module
RPN 3680, RPN 3681	AlkPhos Direct Labeling Module
RPN 3682, RPN 3683	CDP- <i>Star</i> Detection Reagent
RPN 3685, RPN 5750	ECF Detection Module
RPN 3688	AlkPhos Direct Hybridization Buffer
RPN 3690, RPN 3691	AlkPhos Direct Labeling and Detection System with CDP- <i>Star</i>
RPN 3692	AlkPhos Direct Labeling and Detection System with ECF
RPN 5770	Gene Images 3'-Oligolabeling
RPN 5775	Gene Images 3'-Oligolabeling and ECF Signal Amplification
RPN 5776	Gene Images 3'-Oligolabeling and CDP- <i>Star</i> Detection System
US 78500	Thermo Sequenase Cycle Sequencing Kit
US 79565	Thermo Sequenase Dye Terminator Cycle Sequencing Core Kit
US 79765, US 79865, US 79965	Thermo Sequenase Dye Terminator Cycle Sequencing Premix Kit
US 80985	Thermo Sequenase II Dye Terminator Matrix Standards
US 81050, US 81060, US 81070	DYEnamic ET Terminator Cycle Sequencing Kit
US 81090, US 81095	DYEnamic ET Dye Terminator Kit (MegaBACE)
US 82005, US 82010, US 82015	Thermo Sequenase II Dye Terminator Cycle Sequencing Kit